

Remarks

Claims 1-17 are pending. Claims 6-17 are withdrawn from consideration as being directed to a nonelected invention. Therefore, claims 1-5 are presently under examination. No claim has been amended.

Section 101 Rejection (Utility)

In an Advisory Action dated November 26, 2004, the Examiner states that Applicants' previous response has overcome the enablement and Sections 102/103 rejections. The Examiner has maintained the rejection of Claims 1-5 under Section 101 as lacking utility, the only outstanding ground of rejection. Applicants respectfully traverse this rejection in view of previous and new arguments submitted herein.

Applicants reiterate their previous position and incorporate those arguments into the present Response, namely that the present specification sets forth several "real-world" utilities for the present invention which are directly related to known uses of ubiquitin conjugating enzymes that one skilled in the art would readily ascribe to the present invention, including the "diagnosis, treatment or prevention of cancers and tumors, or immune, lymphoproliferative, or neurodegenerative disorders". Moreover, Applicants reiterate their position that the fact that *arguendo* the class of compounds to which the present invention belongs is diverse is not relevant in determining if the present invention has specific and substantial utility in accordance with the PTO's interpretation of Section 101. The requirement for specific and substantial utility is meant to exclude "throw-away" utilities which are unrelated to the "real-world" use of the invention. This is clearly not the case with the present invention in view of such real-world uses stated in the specification and listed above.

Moreover, Applicants now provide further evidence of the utility of the present invention that will be understood and appreciated by one of ordinary skill in the art. As discussed in the Summary of the Invention of this case, the present invention provides a novel polynucleotide encoding a ubiquitin conjugating enzyme homologue, which was isolated from activated human T-cells, and hereinafter designated RATL1d6 ("Regulated in Activated T Lymphocytes 1d6"). RATL1d6 was discovered to be upregulated upon stimulation of Jurkat-line T cells and human peripheral blood T lymphocytes with antibodies directed against the CD3 and CD28 cell surface antigens. The RATL1d6 nucleic acid was identified in a subtraction library from activated human T lymphocytes as described herein. (Specification, page 4, paragraph 11).

Expounding on this, the expression of RATL1d6 was discovered to be increased after stimulation of both a human T-cell line, as well as, primary human T-cells. These cells were

stimulated with antibodies against CD3 and CD28 which provide the physiologically relevant signals for T-cell activation. The discovery that RATL1d6 is upregulated after stimulation of these cells strongly suggests that this gene is critical for either the activation of the T-cell or for the stimulation of immune processes downstream of T-cell activation. For example, interferon-gamma, which is a cytokine which is produced after T-cell activation, plays a critical role in the subsequent activation of macrophages during an in vivo immune response. It is possible that RATL1d6 plays a role in the stimulation of transcription of other cytokines, chemokines or effector molecules critically involved in an immune response. The importance of the CD28 pathway has been validated in humans since abatacept™ (CTLA4-Ig) which inhibits signals via CD28 has been shown to be efficacious in the treatment of rheumatoid arthritis. Prior to the availability of the human data, preclinical data with abatacept™ demonstrated it's utility in animal models of disease. All of these data taken together suggest that RATL1d6, since it's expression is increased after CD3 and CD28 T-cell activation, may play a role in autoimmune disease, and that this utility is understood and appreciated by the those of skill in the art. Accordingly, the present invention clearly has specific and substantial utility in satisfaction of Section 101.

For these reasons, Applicants respectfully submit that the present invention satisfies Section 101 and withdrawal of the outstanding rejection is appropriate and respectfully requested.

Conclusion

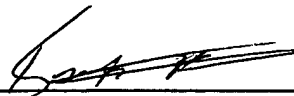
In view of the remarks made herein, Applicants respectfully submit that the claims are in condition for allowance and favorable action is therefore respectfully requested.

Please direct any questions concerning this Response or any aspect of this case to the undersigned attorney.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Account No. 19-3880 in the name of Bristol-Myers Squibb Company.

Respectfully submitted,

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